

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

~~JUDGE RAKOFF~~

HENRIETTA KLEIN, derivatively on
behalf of PFIZER INC.,

Plaintiff,

v.

DENNIS A. AUSIELLO, MICHAEL S.
BROWN, M. ANTHONY BURNS,
ROBERT N. BURT, W. DON
CORNWELL, WILLIAM H. GRAY III,
CONSTANCE J. HORNER, JAMES M.
KILTS, JEFFREY B. KINDLER,
GEORGE A. LORCH, DANA G. MEAD,
SUZANNE NORA JOHNSON, STEPHEN
W. SANGER, WILLIAM C. STEERE, JR.,
FREDA C. LEWIS-HALL, FRANK
D'AMELIO, and IAN READ,

Defendants,

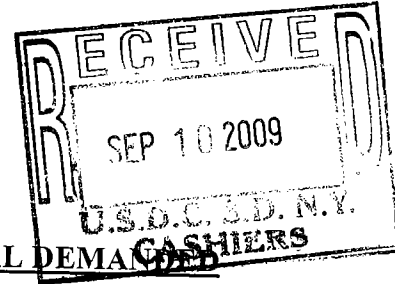
and

PFIZER INC.,

Nominal Defendant.

Civil Action No.

'09 CIV 7822



JURY TRIAL DEMAND

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

1. Plaintiff Henrietta Klein ("Plaintiff"), by and through her undersigned attorneys, hereby submits this Verified Shareholder Derivative Complaint (the "Complaint") for the benefit of nominal defendant Pfizer Inc. ("Pfizer" or the "Company"), against certain current and former members of its Board of Directors (the "Board") and executive officers seeking to remedy defendants' breaches of fiduciary duties and unjust enrichment from 2001 to the present (the "Relevant Period").

NATURE OF THE ACTION

2. This is a shareholder derivative suit to recover damages on behalf of Pfizer arising from false and/or misleading records, statements and claims made, or caused to be made, by

defendants on behalf of Pfizer and Pfizer-owned Pharmacia & Upjohn, Inc. (“Pharmacia”).¹

3. As alleged herein, for years, defendants caused Pfizer and Pharmacia to make thousands of false claims on federal and state health care programs.

4. For instance, starting in at least late 2001, defendants systematically and improperly caused Pfizer to promote prescription drugs, including Bextra, a painkiller which was ultimately removed from the market over safety concerns - for unapproved, off-label uses.

5. In addition, substantial, illegal financial inducements were given to Pfizer’s providers to encourage them to prescribe Bextra and other Pfizer drugs and/or to switch from competitors’ products.

6. These false claims, among other things, cheated federal and state governments out of funds that should not have been paid, unlawfully enriched defendants, and subjected patients to non-approved, non-effective, and unsafe uses and dosages of drugs.

7. As a result of defendants’ actions, the Company ultimately became subject to eleven different civil lawsuits, and criminal charges. Specifically, the government charged that executives and sales representatives throughout Pfizer’s ranks planned and executed schemes to illegally market drugs, which included, among other things, sending doctors on all-expenses-paid trips to expensive resorts and paying kickbacks.

8. As John Kopchinski, a former Company sales representative whose “whistle-blower” complaint in part helped prompt the government’s actions, said, “***The whole culture of Pfizer is driven by sales, and if you didn’t sell drugs illegally, you were not seen as a team player.***”

¹ On April 16, 2003, Pfizer acquired Pharmacia and combined operations to create the world’s largest pharmaceutical company. The new company, operating under the Pfizer name, is one of the world’s largest companies in terms of market capitalization.

9. These lawsuits and charges eventually resulted in the Company and Pharmacia, *inter alia*, paying a record **\$2.3 billion** in civil and criminal fines and penalties to resolve, as disclosed on September 2, 2009. Specifically, Pfizer was required to pay a criminal fine of \$1.195 billion, *the largest criminal fine of any kind ever imposed in the U.S.*, as well as an additional \$1 billion to resolve civil claims, and entered into a “corporate integrity agreement” with Health & Human Services (“HHS”) regarding the Company’s future marketing activities. Meanwhile, Pfizer-owned Pharmacia was required to pay an additional criminal fine of \$105 million. Further, defendants’ actions resulted in Pharmacia pleading **guilty** to one criminal count of felony misbranding under 21 U.S.C. §§ 331(a), 333(a)(2) and 352 of Bextra.

10. Not only was this *the largest health care fraud settlement and largest criminal fine of any kind ever*, it was the fourth Pfizer settlement concerning illegal marketing activities in the last seven years. Previously, the Company had entered into settlement agreements pledging to clean up its drug-marketing practices in 2002 over Lipitor and again in 2004 over Neurotin. In addition, in April 2007, Pfizer-owned Pharmacia pled **guilty to criminal charges** brought by the U.S. Attorney’s Office based on kickbacks offered in connection with the sale of Pfizer’s human growth hormone product, Genotropin. The combined fines leveled against Pfizer in connection with these three settlements in 2002, 2004, and 2007 over its drug marketing practices totaled **\$513 million**.

11. Indeed, as stated by acting U.S. attorney Michael Loucks when the \$2.3 billion in fines were announced on September 2, 2009, “[a]mong the factors we considered in calibrating this severe punishment was Pfizer’s recidivism.” Mr. Loucks added: “[t]he size and seriousness of this resolution, including the huge criminal fine of \$1.3 billion, reflect the seriousness and scope of Pfizer’s crimes. Pfizer violated the law over an extensive time period. Furthermore,

at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws. Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated."

12. Assistant Attorney General Tony West added, "[t]his civil settlement and plea agreement by Pfizer represent yet another example of what penalties will be faced *when a pharmaceutical company puts profits ahead of patient health.*"

13. Importantly, as a result of the **\$2.3 billion** settlement, it became apparent that defendants' actions, specifically with respect to the Company's marketing of drugs for off-label uses, extended beyond the drug Bextra and included the following drugs as well: Geodon (an anti-psychotic drug), Zyvox (an antibiotic), and Lyrica (an epilepsy treatment).

14. Accordingly, the Company has been damaged.

JURISDICTION AND VENUE

15. This Court has jurisdiction over all claims asserted herein pursuant to 28 U.S.C. §1332(a)(2), because complete diversity exists between Plaintiff and each defendant, and the amount in controversy exceeds \$75,000. This action is not a collusive action designed to confer jurisdiction on a court of the United States that it would not otherwise have.

16. This Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in and maintains operations in this District, or is an individual who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the District courts permissible under traditional notions of fair play and substantial justice.

17. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a) because: (i) Pfizer

maintains its principal place of business in the District; (ii) one or more of the defendants either resides in or maintains executive offices in this District; (iii) a substantial portion of the transactions and wrongs complained of herein, including the defendants' primary participation in the wrongful acts detailed herein, and aiding and abetting and conspiracy in violation of fiduciary duties owed to Pfizer occurred in this District; and (iv) defendants have received substantial compensation in this District by doing business here and engaging in numerous activities that had an effect in this District.

THE PARTIES

18. Plaintiff is a current shareholder of Pfizer and has continuously held Pfizer stock at all relevant times. Plaintiff is a citizen of Pennsylvania.

19. Nominal defendant Pfizer is a Delaware corporation headquartered in New York, New York. According to its public filings, Pfizer “engages in the discovery, development, manufacture, and marketing of prescription medicines for humans and animals worldwide.”

20. Defendant Dennis A. Ausiello (“Ausiello”) has served as a director of the Company since 2006. In addition, defendant Ausiello has served as a member of the Board’s Audit Committee (the “Audit Committee”) during the Relevant Period. Further, defendant Ausiello served as a member of the Board’s Corporate Governance Committee (the “Corporate Governance Committee”) during the Relevant Period. Upon information and belief, defendant Ausiello is citizen of Massachusetts.

21. Defendant Michael S. Brown (“Brown”) has served as a director of the Company since 1996. In addition, defendant Brown served as a member of the Corporate Governance Committee during the Relevant Period. Upon information and belief, defendant Brown is a citizen of Texas.

22. Defendant M. Anthony Burns (“Burns”) has served as a director of the Company since 1998. In addition, defendant Burns has served as a member of both the Corporate Governance Committee and the Audit Committee during the Relevant Period. Upon information and belief, defendant Burns is a citizen of Florida.

23. Defendant Robert N. Burt (“Burt”) has served as a director of the Company since 2000. In addition, during the Relevant Period, defendant Burt served as a member of the Audit Committee. Upon information and belief, defendant Burt is a citizen of Illinois.

24. Defendant W. Don Cornwell (“Cornwell”) has served as a director of the Company since 1997. In addition, defendant Cornwell has served as a member of the Audit Committee during the Relevant Period. Upon information and belief, defendant Cornwell is a citizen of New York.

25. Defendant William H. Gray III (“Gray”) has served as a director of the Company since 2000. In addition, defendant Gray served as a member of the Corporate Governance Committee during the Relevant Period. Upon information and belief, defendant Gray is a citizen of Virginia.

26. Defendant Constance J. Horner (“Horner”) has served as a director of the Company since 1993. In addition, defendant Horner served as a member of the Corporate Governance Committee during the Relevant Period. Upon information and belief, defendant Horner is a citizen of Virginia.

27. Defendant James M. Kilts (“Kilts”) has served as a director of the Company since 2007. Upon information and belief, defendant Kilts is a citizen of New York.

28. Defendant Jeffrey B. Kindler (“Kindler”) has served as the Company’s Chief Executive Officer (“CEO”) since July 2006. In addition, defendant Kindler has served as a

director of the Company since July 2006 and as Chairman of the Board since December 2006. During the Relevant Period, prior to becoming CEO of the Company, defendant Kindler served as Vice Chairman and General Counsel from March 2005 to July 30, 2006, Executive Vice President and General Counsel from April 2004 to March 2005, and Senior Vice President and General Counsel from January 2002 to April 2004. Upon information and belief, defendant Kindler is a citizen of New York.

29. Defendant George A. Lorch (“Lorch”) has served as a director of the Company since 2000. Upon information and belief, defendant Lorch is a citizen of Florida.

30. Defendant Dana G. Mead (“Mead”) has served as a director of the Company since 1998. Upon information and belief, defendant Mead is a citizen of Massachusetts.

31. Defendant Suzanne Nora Johnson (“Johnson”) has served as a director of the Company since 2007. In addition, defendant Johnson has served as a member of the Audit Committee during the Relevant Period. Upon information and belief, defendant Johnson is a citizen of New York.

32. Defendant Stephen W. Sanger (“Sanger”) has served as a director of the Company since February 2009. Upon information and belief, defendant Sanger is a citizen of Minnesota.

33. Defendant William C. Steere, Jr. (“Steere”) has served as a director of the Company since 1987. In addition defendant Steere has served as Chairman Emeritus of the Company since July 2001. Further, defendant Steere previously served as Chairman of the Board from 1992 to April 2001 and CEO from 1991 to 2000. Upon information and belief, defendant Steere is a citizen of New York.

34. Defendant Freda C. Lewis-Hall (“Lewis-Hall”) has served as the Company’s Chief Medical Officer during the Relevant Period. Upon information and belief, defendant

Lewis-Hall is a citizen of New York.

35. Defendant Frank D'Amelio ("D'Amelio") has served as Chief Financial Officer ("CFO") of the Company during the Relevant Period. Upon information and belief, defendant D'Amelio is a citizen of New York.

36. Defendant Ian Read ("Read") has served as Senior Vice President and President, Worldwide Pharmaceutical Operations for the Company during the Relevant Period. Upon information and belief, defendant Read is a citizen of New York.

37. Collectively, defendants Ausiello, Burns, Cornwell, Burt, and Johnson shall be referred to as the "Audit Committee Defendants."

38. Collectively, defendants Ausiello, Brown, Burns, Gray, and Horner shall be referred to as the "Corporate Governance Committee Defendants."

39. Collectively, defendants Ausiello, Brown, Burns, Burt, Cornwell, Gray, Horner, Kilts, Kindler, Lorch, Mead, Johnson, Sanger, Steere, Lewis-Hall, D'Amelio, and Read shall be referred to as "Defendants."

DEFENDANTS' DUTIES

40. By reason of their positions as officers, directors, and/or fiduciaries of Pfizer and because of their ability to control the business and corporate affairs of Pfizer, Defendants owed Pfizer and its shareholders fiduciary obligations of good faith, loyalty, and candor, and were and are required to use their utmost ability to control and manage Pfizer in a fair, just, honest, and equitable manner. Defendants were and are required to act in furtherance of the best interests of Pfizer and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit. Each director and officer of the Company owes to Pfizer and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the

affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

41. Defendants, because of their positions of control and authority as directors and/or officers of Pfizer, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein. Because of their advisory, executive, managerial, and directorial positions with Pfizer, each of the Defendants had knowledge of material non-public information regarding the Company.

42. To discharge their duties, the officers and directors of Pfizer were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of Pfizer were required to, among other things:

- a. Exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of their business;
- b. Exercise good faith to ensure that the Company was operated in a diligent, honest and prudent manner and complied with all applicable federal and state laws, rules, regulations and requirements, and all contractual obligations, including acting only within the scope of its legal authority; and
- c. When put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

43. Further, every member of the Board is obligated to comply with the Company's Code of Business Conduct and Ethics for Directors, which provides, *inter alia*:

- a. That "[d]irectors must comply, and oversee compliance by employees, officers and other directors with laws, rules, and regulations applicable to the Company" and
- b. That "[d]irectors must deal fairly, and must oversee fair dealing by employees and officers, with the Company's customers, suppliers, competitors and employees."

44. Pursuant to the Audit Committee's Charter, the members of the Audit Committee are required, *inter alia*, to:

- a. Review the status of compliance with laws, regulations, and internal procedures;
- b. Review the scope and status of systems designed to promote Company compliance with laws, regulations and internal procedures;
- c. Review contingent liabilities and risks that may be material to the Company; and
- d. Review major legislative and regulatory developments which could materially impact the Company's contingent liabilities and risks.

45. Pursuant to the Corporate Governance Committee's Charter, the members of the Corporate Governance Committee are required, *inter alia*, to:

- a. Consider matters of corporate governance; and
- b. Maintain an informed status on Company issues related to corporate social responsibility.

SUBSTANTIVE ALLEGATIONS

Background of the Company

46. Pfizer was founded in 1849 as Charles Pfizer and Co., a chemicals business. Over the last century, it has aligned itself with the developing trends to become a research-based pharmaceutical company. Notably, Pfizer produced most of the penicillin used during World War II. Pfizer is now the world's largest pharmaceutical company, with over **\$48 billion** in revenues in 2007.

47. On April 16, 2003, Pfizer acquired Pharmacia and combined operations to create the world's largest pharmaceutical company. The newly formed Company, operating under the Pfizer name, is one of the world's largest companies in terms of market capitalization.

48. According to its public filings, Pfizer currently “engages in the discovery, development, manufacture, and marketing of prescription medicines for humans and animals worldwide.”

History of Bextra

49. Bextra is Pfizer's trade name for the drug valdecoxib. Bextra/valdecoxib is a so-called "COX-2 Inhibitor." The "COX-2" class of drugs includes the previously released drug Celebrex, which is also marketed by Pfizer, and the competing drug Vioxx, manufactured by Merck. The COX-2 class of drugs is designed to relieve various forms of pain and inflammation.

50. In November 2001, Bextra was first approved by the FDA for relief of the symptoms of osteoarthritis and adult rheumatoid arthritis, and for treatment of primary dysmenorrhea. Significantly, Pfizer had also sought approval for several additional indications, including acute pain, pre-operative dosing and opiod sparing, but was rejected by the FDA.

51. Since Bextra's FDA-approval, Pfizer has sought to expand its approved indication only once.

52. Bextra's narrow FDA-approved indication limits the potential sales growth of the drug, particularly in view of the fact that numerous other approved pain medications are also available to the public.

53. As alleged below, to grow drug sales in a constrained environment, Defendants resorted to marketing strategies prohibited by federal law, including kickback schemes and off-label promotion.

54. Also as alleged below, Defendants circumvented federally mandated FDA approval processes by aggressively marketing Bextra for numerous unapproved uses - including, but not limited to, treatment for general acute pain; chronic arthritis at doses greater than 10

mg/day; pre-surgical dosing; and, post-surgical pain, among many others. Indeed, Pfizer's requests for approval for treatment for acute pain other than dysmenorrhea; chronic arthritis at doses greater than 10 mg/day; and dysmenorrhea at doses greater than two 20 mg doses/day, were specifically rejected by the FDA.

55. In addition, Defendants have caused the Company to violate federal anti-kickback laws by paying and offering to pay financial inducements to physicians and other providers to influence their Bextra prescribing practices.

Applicable Laws and Regulations Governing Pfizer's Operations

A. Prescription Drug Reimbursement Under Medicaid and Other Federal Health Care Programs

56. Medicaid is a public assistance program providing for payment of medical expenses for the poor and disabled. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

57. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding, which is called federal financial participation. 42 U.S.C. §§1396 *et seq.*

58. Federal reimbursement for prescription drugs under the Medicaid program is available for "covered outpatient drugs." 42 U.S.C. §1396b(I)(10), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." *Id.* §1396r8(k)(3).

59. A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or that is included in one of the drug compendia identified in the Medicaid statute. *Id.* §1396r-8(k)(6).

60. During the Relevant Period, with one exception, the off-label uses of Bextra promoted by Defendants were not eligible for reimbursement from Medicaid because the drug's off-label uses were neither listed in the labeling approved by the FDA nor included in the drug compendia specified by the Medicaid statute.

61. That single exception, as noted in the Drugdex compendia, is for treatment of post-operative pain. However, even with respect to this limited off-label use identified by Drugdex, any prescriptions written prior to Drugdex's inclusion of post-operative pain as an off-label indication, were not entitled to reimbursement under Medicaid.

B. FDA Prohibition on Promotion of Off-Label Indications

62. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. M301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. §355(a) & (d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

63. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may be prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

64. The indications and dosages approved by the FDA are set forth in the drug's labeling, the content of which must also be reviewed and approved by the FDA. 21 U.S.C. §§352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d).

65. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for alternative uses - *i.e.*, uses not listed on the approved label - the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. §360aaa(b) & c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off- label."

66. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (*e.g.*, treating a child when the drug is approved to treat adults).

67. The FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication. However, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different than those approved by the FDA.

68. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331, 352.

69. An off-label use of a drug can cease to be off label only if the manufacturer

submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. §360aaa(b) & (c).

70. In sum, the FDCA prohibits drug companies from promoting approved drugs for unapproved uses or from making misleading claims as to the drug's safety or effectiveness. *See* 21 U.S.C. §§ 331, 352, 355(d). This off-label regulatory scheme protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body, the FDA.

71. Throughout the Relevant Period, as indicated below, Defendants caused the Company to improperly market numerous of its drugs including Bextra, Geodon, Zyvox, and Lyrica for numerous off-label uses.

C. The Anti-Kickback Statute

72. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

73. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b).

74. Under this statute, drug companies may not offer or pay any remuneration, in cash

or kind, directly or indirectly, to induce physicians or others to order or recommend drugs that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company that has as one of its purposes inducement of a physician to write additional prescriptions for the company's pharmaceutical products.

75. Violation of the Anti-Kickback statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§1320a-7(b)(7), 1320a-7a(a)(7).

The Truth Emerges in September 2009

76. Instead of ensuring that the Company abided by the above-discussed laws and regulations, as Defendants are required to do, Defendants instead caused the Company to engage in numerous violations of federal and state laws, which severely damaged the Company, causing it to be responsible for payment of record fines.

77. The result of Defendants' actions were revealed on September 2, 2009. In an article entitled "Pfizer in \$2.3B Drug-Marketing Case Settlement," the *Wall Street Journal* revealed that the Company had been engaged in multiple violations of the above-cited laws (and/or substantially similar other federal and state laws and regulations) and eventually paid **\$2.3 billion** in civil and criminal penalties and fines. Specifically, the article stated:

WASHINGTON (Dow Jones)--Pfizer Inc. (PFE) has agreed to pay \$2.3 billion to settle criminal and civil charges that it illegally marketed the pain drug Bextra and three other medicines for uses that weren't approved by the Food and Drug Administration, the U.S. Justice Department announced Wednesday.

The agreement, the largest health-care fraud settlement in the department's history, calls for Pfizer to pay \$1.3 billion in criminal fines and forfeitures and another \$1 billion in civil fines. As part of the settlement, Pfizer subsidiary Pharmacia & Upjohn Co. will plead guilty to a felony violation in connection with the improper promotion of Bextra.

Pfizer also will enter into a monitoring agreement that government officials described as unprecedented. The company will have to create a mechanism doctors can use to report questionable conduct by Pfizer sales representatives, and it must post information online about its payments and gifts to doctors.

Any violations of the agreement could lead to additional fines and possible exclusion from participating in government health-care programs.

Along with Bextra, authorities alleged Pfizer improperly promoted anti-psychotic drug Geodon, antibiotic drug Zyvox and epilepsy drug Lyrica.

Authorities also said the drug maker paid kickbacks - including entertainment, cash, travel and meals - to doctors who prescribed those four drugs and nine other Pfizer offerings, including cholesterol drug Lipitor and impotence drug Viagra.

Department lawyers said the penalties were steep because Pfizer is a repeat offender, with four Justice Department settlements this decade.

"One of the factors we considered in calibrating this severe punishment is Pfizer's recidivism," said Michael Loucks, the U.S. attorney in Massachusetts.

Pfizer alerted investors in January that a settlement was near, saying in an earnings release that it took a \$2.3 billion charge in the fourth quarter of 2008 to cover the cost of the settlement. That announcement came the same day the New York drug maker said it was acquiring New Jersey-based Wyeth in a \$68 billion deal.

Amy W. Schulman, senior vice president and general counsel of Pfizer, said in a statement Wednesday that the drug maker regretted "certain actions taken in the past," but she said the company had taken corrective actions.

Schulman said the settlement gave Pfizer "final closure to significant legal matters."

Pfizer pulled Bextra from the market in 2005 because the FDA concluded its risks, including a rare but serious skin reaction, outweighed its benefit.

The Justice Department said Pfizer promoted Bextra for several uses and dosages that the FDA specifically declined to approve because of safety concerns.

The FDA approved Bextra in 2001 to treat arthritis and menstrual pain. But the Justice Department said Pfizer also marketed the drug to treat acute pain and surgical pain - at dosages above the maximum levels approved by the FDA.

Government officials said Pfizer made false and misleading claims about the drug's safety, and pushed the drug on doctors for unapproved uses.

Officials said Pfizer's allegedly fraudulent marketing caused false claims to be submitted to government health-care programs such as Medicaid and Medicare, which paid for unapproved uses of Bextra and other drugs.

The government's investigation was spurred by several whistle-blower complaints alleging misconduct by Pfizer. As part of the settlement, six whistle-blowers - five

Pfizer employees and a doctor in Pennsylvania - will receive payments totaling \$102 million.

Pfizer said it expressly denies all of the government's civil allegations, except it acknowledged "certain improper actions" related to the promotion of Zyvox.

The company also said Wednesday it will pay \$33 million to 42 states and the District of Columbia to settle state civil consumer protection allegations related to its past promotional practices concerning Geodon. A charge in that amount will be recorded this quarter.

Bextra's troubles began in 2004 when Vioxx, Merck & Co.'s (MRK) popular non-steroidal painkiller somewhat similar to Bextra, was withdrawn from the market after being linked to heart attacks. That November, during a Senate hearing on Vioxx, a whistle-blower from the FDA testified that he believed five other prominent drugs should also be withdrawn because of safety issues, and named Bextra as one.

Pfizer's other non-steroidal painkiller, Celebrex, hasn't been withdrawn, but last October the company agreed to pay \$894 million to settle a series of state, personal-injury and class-action lawsuits involving both drugs.

78. In connection with the settlement, the U.S. Department of Health & Human Services and U.S. Department of Justice constructed a website located at: <http://www.stopmedicarefraud.gov/pfizerfactsheet.html> (the "DOJ Website"), which specifically laid out the Company's violations and repercussions. In connection with Defendants "off-label" uses for the various drugs, the DOJ Website provided as follows:

Bextra

FDA Approved Indications	Off-Label Uses Promoted
<ul style="list-style-type: none"> – Osteoarthritis – Adult rheumatoid arthritis – Primary dysmenorrhea 	<ul style="list-style-type: none"> – Acute pain – Various types of surgical pain – Dosages above approved maximum

Geodon

FDA Approved Indications	Off-Label Uses Promoted

<ul style="list-style-type: none"> – Schizophrenia – Acute manic or mixed episodes associated with bipolar disorder – Geodon Intramuscular is indicated for treatment of acute agitation in schizophrenic patients for whom treatment with Geodon is appropriate 	<ul style="list-style-type: none"> – Depression – Bipolar maintenance – Mood disorder – Anxiety – Aggression – Dementia – Attention Deficit Hyperactivity Disorder – Obsessive compulsive disorder – Autism – Posttraumatic stress disorder – Unapproved patient populations (including pediatric and adolescent patients) – Dosages above approved maximum
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Zyvox

FDA Approved Indications	Off-Label Uses Promoted
<ul style="list-style-type: none"> – Vancomycin-Resistant <i>Enterococcus faecium</i> infections – Nosocomial pneumonia – Community-acquired pneumonia – Complicated skin and skin structure infections (including diabetic foot infections without concomitant osteomyelitis) 	<ul style="list-style-type: none"> – Infections caused by methicillin-resistant <i>Staphylococcus aureus</i> (“MRSA”) generally, rather than only those types of MRSA infections for which Zyvox was FDA-approved

Lyrica

FDA Approved Indications	Off-Label Uses Promoted

<ul style="list-style-type: none"> – Adjunctive therapy for adults with partial onset seizures – Management of post-herpetic neuralgia – Management of neuropathic pain associated with diabetic peripheral neuropathy – Fibromyalgia 	<ul style="list-style-type: none"> – Chronic pain – Neuropathic pain – Perioperative pain – Migraine
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79. The DOJ Website also states the following regarding the Company's kickback violations:

- Resolves allegations that Pfizer violated the federal False Claims Act by knowingly causing false or fraudulent claims to be submitted to, or causing purchases by, Medicaid, Medicare and other federal health care programs by:

* * *

- Paying kickbacks to health care providers to induce them to prescribe Bextra, Geodon, Zyvox, and Lyrica;
- Paying kickbacks to health care providers in connection with its marketing of nine other drugs: Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, and Zyrtec (Kickback Drugs)

80. The DOJ Website further provides that the Company is now subject to the following "Administrative Resolution:"

Administrative Resolution

- Pfizer has entered into a comprehensive five-year Corporate Integrity Agreement with the Office of Inspector General, Department of Health and Human Services
- Requires enhanced accountability, increased transparency, and wide-ranging monitoring activities conducted by both internal and independent external reviewers
 - Also requires:
 - that Audit Committee of Pfizer's Board of Directors annually review the company's compliance program and certify as to its effectiveness;

- that senior executives annually certify about compliance:
- that Pfizer notify doctors about the global settlement and establish a mechanism doctors can use to report questionable conduct by any Pfizer representative; and
- that the company post on its Web site information about payments to doctors, such as honoraria, travel, or lodging
- First Corporate Integrity Agreement to require that a pharmaceutical manufacturer proactively identify potential risks associated with promoting individual products and that it implement a plan to mitigate the identified risks
- If Pfizer fails to comply with its obligations, it risks exclusion from Federal health care programs and monetary penalties

81. Most notably, however, this is hardly the first time in which Pfizer has come under fire -- and faced *criminal* penalties -- for similar misconduct. Specifically, the Company was previously forced to sign “corporate integrity” agreements pledging to clean up its drug-marketing practices in 2002 over Lipitor and again in 2004 over Neurotin. In addition, most recently, in April 2007, Pfizer-owned Pharmacia pled *guilty to criminal charges* brought by the U.S. Attorney’s Officer in connection with offering kickbacks in connection with the sale of its human growth hormone product, Genotropin.² Further, at that time, the Company also entered into a deferred prosecution agreement for illegally promoting Genotropin for multiple off-label uses. Accordingly, the Company was forced to pay approximately **\$34.7 million** in fines and penalties arising from these events, including a criminal fine of \$19.98 million.

82. As a result of Defendants’ actions, they have caused the Company to incur

² Genotropin was approved by the FDA solely for the treatment of children with growth related diseases. Instead, however, Pharmacia engaged in the unlawful promotion of Genotropin for uses not approved by the FDA such as anti-aging, cosmetic use, and athletic performance enhancement. In addition, Pharmacia violated the federal anti-kickback law by offering to make \$12.3 million in excess payments on a distribution to a pharmacy benefit manager in the expectation of obtaining improved positioning for Genotropin and other products.

significant damages.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

83. Plaintiff brings this action derivatively in the right and for the benefit of Pfizer to redress the breaches of fiduciary duty and other violations of law by Defendants.

84. Plaintiff will adequately and fairly represent the interests of Pfizer and its shareholders in enforcing and prosecuting its rights.

85. The Board currently consists of the following fourteen (14) individuals: defendants Ausiello, Brown, Burns, Burt, Cornwell, Gray, Horner, Kilts, Kindler, Lorch, Mead, Johnson, Sanger, and Steere. Plaintiff has not made any demand on the Board to institute this action because such a demand would be a futile, wasteful and useless act, for the following reasons:

- a. Every member of the Board is required to comply with the Company's Code of Business Conduct and Ethics for Directors (the "Code"). The Code requires each of the Company's directors to "comply, and oversee compliance by employees, officers, and other directors, with laws, rules and regulations applicable to the Company." Further, the Code requires directors to "deal fairly...and oversee fair dealing by employees and officers, with the Company's customers, suppliers, competitors and employees." Each member of the Board permitted individuals at all levels of the Company to engage in the illicit conduct described above, thereby abdicating their fiduciary duties to the Company, and severely damaging the Company. Therefore, every member of the Board faces a substantial likelihood of liability for their breaches of fiduciary duties and any demand upon them is futile;
- b. Every member of the Board was aware of, or should have been aware of, numerous red flags regarding the Company's illicit marketing practices. Specifically, as discussed above, the Company has entered into multiple "corporate integrity" agreements over the last several years in which it pledged to clean up its drug-marketing practices. Further, the Company was forced to pay \$34.7 million in fines and penalties as recently as April 2007 in connection with Defendants' unlawful marketing practices concerning Genotropin. Despite clearly being placed on notice of illicit practices, Defendants consciously disregarded their fiduciary duties to Pfizer when, under their direction, the Company continued to expend resources to market its products for "off-label" uses and engage in other illicit marketing activities;

- c. At various points during the Relevant Period, defendants Ausiello, Burns, Cornwell, and Johnson served as members of the Audit Committee. Pursuant to the Company's Audit Committee Charter, the members of the Audit Committee are charged with reviewing the Company's compliance with laws, regulations, and internal procedures. Defendants Ausiello, Burns, Cornwell, and Johnson breached their fiduciary duties of due care, loyalty, and good faith, because the Audit Committee permitted the Company to repeatedly violate the laws and regulations as discussed above, despite the fact that they were on notice of the Company's illicit marketing activities. Therefore, defendants Ausiello, Burns, Cornwell, and Johnson face a substantial likelihood of liability for their breach of fiduciary duties and any demand upon them is futile;
- d. During the Relevant Period, defendants Ausiello, Brown, Burns, Gray, and Horner served as members of the Corporate Governance Committee. Pursuant to the Corporate Governance Committee Charter, the members of the Corporate Governance Committee are charged with reviewing matters of corporate governance and maintaining an informed status on Company issues related to corporate social responsibility. Defendants Ausiello, Brown, Burns, Gray, and Horner breached their fiduciary duties of due care, loyalty, and good faith, as the Company-wide conduct described above, including the fraudulent promotion of drugs and the paying of kickbacks, which ultimately resulted in a record \$2.3 billion in fines, clearly demonstrates that the Governance Committee failed to ensure that the Company acted in a "socially responsible" manner. Therefore, defendants Ausiello, Brown, Burns, Gray, and Horner face a substantial likelihood of liability for their breach of fiduciary duties and any demand upon them is futile;
- e. The principal professional occupation of defendant Kindler is his employment with Pfizer as its CEO, pursuant to which he has received and continues to receive substantial monetary compensation and other valuable benefits. Thus, defendant Kindler lacks independence, rendering him incapable of impartially considering a demand to commence and vigorously prosecute this action;
- f. By the Board's own admission, defendant Steere lacks independence. Specifically, defendant Steere is the former CEO and Chairman of the Company, pursuant to which he has received substantial monetary compensation and other valuable benefits. Further, defendant Steele is currently the Chairman Emeritus of the Company, pursuant to which he earns director fees of at least \$275,000 per year. Thus, in accordance with the Board's own admission, defendant Steere lacks independence, rendering him incapable of impartially considering a demand to commence and vigorously prosecute this action.

COUNT I
AGAINST ALL DEFENDANTS FOR BREACH OF FIDUCIARY
DUTIES FOR FAILING TO MAINTAIN INTERNAL CONTROLS

86. Plaintiff incorporates by reference all preceding and subsequent paragraphs as if fully set forth herein.

87. As alleged herein, each of the Defendants had a fiduciary duty to, among other things, exercise good faith to ensure that the Company was in compliance with all laws and regulations.

88. Defendants willfully ignored the obvious and pervasive problems with Pfizer's internal controls practices and procedures and failed to make a good faith effort to correct the problems or prevent their recurrence.

89. As a direct and proximate result of the Defendants' foregoing breaches of fiduciary duties, the Company has sustained damages.

COUNT II
AGAINST ALL DEFENDANTS FOR BREACH OF FIDUCIARY DUTIES FOR
FAILING TO PROPERLY OVERSEE AND MANAGE THE COMPANY

90. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

91. Defendants owed and owe Pfizer fiduciary obligations. By reason of their fiduciary relationships, Defendants specifically owed and owe Pfizer the highest obligation of good faith, fair dealing, loyalty and due care.

92. Defendants, and each of them, violated and breached their fiduciary duties of due care, loyalty, reasonable inquiry, oversight, good faith and supervision.

93. As a direct and proximate result of Defendants' failure to perform their fiduciary obligations, Pfizer has sustained significant damages, not only monetarily, but also to its corporate image and goodwill.

94. As a result of the misconduct alleged herein, Defendants are liable to the Company.

95. Plaintiff, on behalf of Pfizer, has no adequate remedy at law.

**COUNT III
AGAINST ALL DEFENDANTS FOR UNJUST ENRICHMENT**

96. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

97. By their wrongful acts and omissions, the Defendants were unjustly enriched at the expense of and to the detriment of Pfizer.

98. Plaintiff, as a shareholder and representative of Pfizer, seeks restitution from these Defendants, and each of them, and seeks an order of this Court disgorging all profits, benefits and other compensation obtained by these Defendants, and each of them, from their wrongful conduct and fiduciary breaches.

**COUNT IV
AGAINST ALL DEFENDANTS FOR ABUSE OF CONTROL**

99. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

100. Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Pfizer, for which they are legally responsible. In particular, Defendants abused their positions of authority by causing or allowing Pfizer to engage in the wrongful conduct described above.

101. As a direct and proximate result of Defendants' abuse of control, Pfizer has sustained significant damages.

102. As a result of the misconduct alleged herein, Defendants are liable to the Company.

103. Plaintiff, on behalf of Pfizer, has no adequate remedy at law.

**COUNT V
AGAINST ALL DEFENDANTS FOR GROSS MISMANAGEMENT**

104. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

105. Defendants had a duty to Pfizer and its shareholders to prudently supervise, manage and control the operations, business and internal financial accounting and disclosure controls of Pfizer.

106. Defendants, by their actions and by engaging in the wrongdoing described herein, abandoned and abdicated their responsibilities and duties with regard to prudently managing the businesses of Pfizer in a manner consistent with the duties imposed upon them by law. By committing the misconduct alleged herein, Defendants breached their duties of due care, diligence and candor in the management and administration of Pfizer's affairs and in the use and preservation of Pfizer's assets.

107. During the course of the discharge of their duties, Defendants knew or recklessly disregarded the unreasonable risks and losses associated with their misconduct, yet Defendants caused Pfizer to engage in the scheme complained of herein which they knew had an unreasonable risk of damage to Pfizer, thus breaching their duties to the Company. As a result, Defendants grossly mismanaged Pfizer.

**COUNT VI
AGAINST ALL DEFENDANTS FOR WASTE OF CORPORATE ASSETS**

108. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

109. As a result of the misconduct described above, and by failing to properly consider the interests of the Company and its public shareholders, Defendants have caused Pfizer to incur

(and Pfizer may continue to incur) significant legal liability and/or legal costs to defend itself as a result of Defendants' unlawful actions.

110. As a result of this waste of corporate assets, Defendants are liable to the Company.

111. Plaintiff, on behalf of Pfizer, has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Against all Defendants and in favor of the Company for the amount of damages sustained by the Company as a result of Defendants' breaches of fiduciary duties;

B. Directing Pfizer to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect the Company and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote resolutions for amendments to the Company's By-Laws or Articles of Incorporation and taking such other action as may be necessary to place before shareholders for a vote a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the Board

C. Awarding to Pfizer restitution from Defendants, and each of them, and ordering disgorgement of all profits, benefits and other compensation obtained by the Defendants;

D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

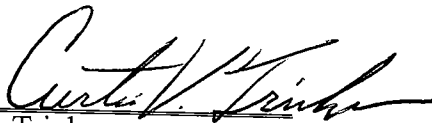
E. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: September 10, 2009

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PFIZER INC. VERIFICATION

I, Henrietta Klein, hereby verify that I am familiar with the allegations in the Complaint, and that I have authorized the filing of the Complaint, and that the foregoing is true and correct to the best of my knowledge, information, and belief.

Date: _____

9/8/09


Henrietta Klein